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## **Summary and keywords**

### **Summary**

Patients presenting with periorbital trauma require clinical assessment to exclude zygomatico-maxillary fractures. A single-centre pilot investigation was undertaken at a general hospital in the United Kingdom. The sample was composed of 229 adult patients attending our emergency department with periorbital injuries. Findings from 17 signs or symptoms of facial injury were recorded on a validated tool. The relationship between clinical presentation and displaced zygomatico-maxillary fracture was assessed using diagnostic test parameters and tests for correlation. A decision-making rule was derived. The presence of a) palpable bony step, b) bony asymmetry, c) lateral sub-conjunctival haemorrhage with no posterior limit, d) anaesthesia or paraesthesia to lip/cheek or side of nose and e) palpable emphysema were all specific features of radiographically displaced zygomatico-maxillary fracture (specificity all >75.0 %, *p* value for correlation all < 0.001). A decision-making rule based on the presence of any one of features (a),(c),(d) or (e) identified all patients with displaced zygomatico-maxillary fractures in this sample (sensitivity 100% (95% CI 93.4% - 100.0%), specificity 72.6% (95% CI 65.3% - 79.0%). Implementation of this clinical decision-making rule would identify all patients with displaced fractures at the triage stage whilst reducing radiographic exposures by 55% in this sample.

**Keywords:** Facial trauma; Zygomatico-maxillary fractures; Zygomatic fractures; Clinical examination; Radiographic examination; Clinical decision rules

## INTRODUCTION

Facial trauma is a common presentation to the Emergency Department(*Ceallaigh et al. 2006*). For patients with trauma to the periorbital region there is often suspicion of bony injuries. Non-specialist healthcare practitioners are required to identify patients who require radiographic imaging, or seek specialist referral.

In recent years, clinical decision making rules have been adopted for a number of bony injuries (*Adams and Leveson 2012*), including the Ottawa rules to identify fractures of the ankle(*Stiell et al. 1992*) or knee(*Stiell et al. 1997*), and Canadian cervical spine rules(*Stiell et al. 1992, Stiell et al. 1997, Stiell et al. 2001*). Reliable identification of patients without significant bony injuries based on clinical features alone may result in improvement in patient experience and safety through reduced time spent in hospital(*Nichol et al. 1999*) or fewer radiographic investigations(*Jenny et al. 2005*). In contrast to other bony injuries, there has been little work to develop or validate clinical decision rules for zygomatico-maxillary fractures.

Patients with fractures requiring surgery (i.e. displaced fractures) have identifiable clinical differences from patients presenting with facial injuries suitable for conservative management (*Salentijn et al. 2014a*). Extra-oral steps and intra-oral steps are more common in patients with displaced fractures than in those with undisplaced fractures, whereas facial swelling is found frequently regardless of fracture displacement(*Salentijn et al. 2014a*). In a 10 year retrospective study by Salentijn et al, sensory disturbance in the infra-orbital region, periorbital haematoma, malar depression, facial swelling and bony steps were all common features of bony injuries requiring surgical management(*Salentijn et al. 2013*), however the relationship between these clinical findings and undisplaced fractures, or isolated soft tissue injuries was not examined. Therefore, it remains unknown whether these features might identify patients with displaced fractures.

This pilot investigation aimed to use prospectively recorded clinical data to assess whether clinical decision rules could help identify patients with a radiographically displaced zygomatico maxillary fracture.

## **MATERIAL AND METHOD**

Approval was obtained following review by Gloucestershire Hospitals NHS Foundation Trust audit committee (log number 1860). Data reported in these analyses was obtained in ad district general hospital in the United Kingdom, between December 2013 and May 2016. At inception, a validated, structured facial-injury record-keeping tool was introduced into routine clinical use. This provided a template for structured prospective examination and record keeping of 17 signs or symptoms of facial injury, and was designed for patients with suspected zygomatico maxillary fracture. Our experience using this structured record keeping tool is reported in detail(*Haworth et al.* 2015).

The inclusion criteria were as follows; a) adult patients (aged 18 or older at time of assessment) b) initial assessment in the Emergency Department for a suspected periorbital injury c) diagnostic radiographs available (occipito-mental 10 and 30 degree plain facial radiographs) d) conscious at time of initial assessment and e) complete and prospectively recorded clinical data on all 17 signs and symptoms available. Exclusion criteria were patients with suspected or confirmed isolated orbital floor fracture.

During the study period, 235 patients met the inclusion criteria. Six patients were excluded from analysis for suspected or confirmed isolated orbital floor fracture, leaving 229 cases for analysis.

All radiographic reports and radiographic imaging were reviewed by a single (unblinded) author using a workstation compliant with the minimum specifications outlined by the Royal College of Radiologists(*Radiologists* 2012). Each radiograph was classified based on the presence or absence of radiographic findings in keeping with a displaced fracture. Radiographic anomalies such as a fluid

level in the maxillary sinus were not considered evidence of a displaced fracture in the absence of other radiographic evidence.

Anonymized data was analysed in accordance with local guidelines. Initially we tested for correlation between clinical features and radiographic findings and evaluated the performance of 17 clinical features as predictors of a radiographically displaced fracture. For this evaluation, the predictor variable was presence or absence of a clinical feature and the outcome variable was presence or absence of radiographic evidence of a displaced fracture. The test statistics used were sensitivity, specificity and Receiver Operating Curve (ROC) area, which measures overall ability to predict the presence or absence of a fracture correctly taking account of both sensitivity and specificity. We ranked all 17 clinical features based on their Receiver Operating Curve (ROC) area.

For the next stage of analysis we selected a subset of features with a statistically significant association with the presence of a displaced fracture after correction for multiple testing ( $p < 0.0029$ ) and predictive ability (95% confidence intervals for ROC area excluding 0.5). We examined the ability of different combinations of these clinical features to correctly predict the presence or absence of a radiographically displaced fracture. When evaluating combinations of features, a positive test was defined as the presence of one or more features, whereas a negative test was defined as the absence of all clinical features in that particular combination. As before, the clinical findings were used as the predictor variable and the outcome variable was the presence or absence of a radiographically displaced fracture. All statistical analysis was performed using the statistical package Stata. (*StataCorp* 2015)

Finally, we took the single most predictive combination of clinical features and explored whether this has potential as a clinical decision-making rule. We retrospectively assessed the impact of this candidate clinical decision-making rule on the proportion of fractures identified at triage stage, proportion of patients undergoing radiographic investigation and diagnostic yield of radiographs.



## RESULTS.

Overall, 54 patients (23.6 %; 95% C.I.18.2%– 29.6%) had radiographic evidence of a displaced fracture.

### **Clinical features as a predictor of displaced zygomatic-maxillary fracture.**

No single clinical feature was seen in every patient with a displaced fracture. The presence of palpable bony steps was the most sensitive and specific single clinical feature (sensitivity 83.3% (95% CI 70.7-92.1%), specificity 96.0% (95% CI 91.9-98.4%), ROC area 0.90 (95% CI 0.84-0.95), *p* value for correlation < 0.001. By contrast, other features such as severe soft tissue swelling performed poorly as a predictor of radiographic evidence of a displaced fracture (sensitivity 40.7% (95% CI 27.6-55.0%), specificity 57.1% (95% CI 49.5-64.6), ROC area 0.49 (95% CI 0.41-0.57), *p* value for correlation 0.78. The results for all clinical features assessed are provided (Table 1).

### **Highly informative clinical features**

Five clinical features met the criteria for inclusion in our subset of highly informative clinical features. These were a) palpable bony step, b) bony asymmetry, c) lateral sub-conjunctival haemorrhage with no posterior limit, d) anaesthesia or paraesthesia to lip/cheek or side of nose and e) palpable emphysema. One or more of these features was present in every patient with a displaced fracture in this population. The most predictive combination of features was the presence of any one of a), c), d) or e). Within our data this combination of features was 100.0% sensitive (95% CI 93.4% - 100.0%) whilst maintaining 72.6% specificity (95% CI 65.3% - 79.0%) for presence of a displaced fracture. The diagnostic parameters for this combination of features are shown in full in table 2. Specificity improved with combinations which required two or more clinical features to be present. Several rules based on combinations of clinical features were 100% specific, including the presence of bony asymmetry with sub-conjunctival hemorrhage with no posterior limit (95% CI for

specificity 97.% - 100%), however these rules had reduced sensitivity compared to single clinical features (42.6%, 95% CI 29.2% - 56.8%).

#### **Performance of a candidate clinical decision making rule.**

We retrospectively explored whether the combination of features described in table 2 could be used as a decision-making rule. If patients had been triaged based on the presence or absence of these four clinical features, 102 patients would have proceeded to radiographic examination whilst 127 patients would have been discharged without radiographs, achieving a reduction of 55.5% (95% CI 49.0% - 61.9%) in the use of radiographs, whilst still identifying all displaced fractures at the triage stage. The diagnostic yield of radiographs would have improved from 23.6% to 52.9%. This is illustrated in figure 1.



## DISCUSSION

In keeping with previously published evidence, this study has identified that bony steps and paraesthesia in the distribution of the infra-orbital nerve are associated with displaced zygomatico-maxillary fractures. In addition, this study identifies that bony asymmetry, lateral sub-conjunctival haemorrhage with no posterior limit and palpable emphysema are also specific features of displaced zygomatico-maxillary fractures (specificity all >75%). We believe that this is the first published evidence demonstrating these features which are informative when diagnosing zygomatico-maxillary fractures.

Evidence shows that predictive models derived in small datasets can become overfitted and perform poorly in subsequent validation, especially when large numbers of parameters are fitted. (Stiell and Wells 1999) With this in mind, we initially created a small subset of highly informative and significantly associated clinical features, and only considered these features when deriving a candidate clinical decision making rule. Before this candidate decision rule is ready for adoption into routine clinical practice a larger study is required to validate the rule, and we hope that this pilot study will stimulate interest in clinical decision rules for zygomatico-maxillary fractures, and provide data for further research. We suggest with further refinement, an algorithm similar to that devised in Ottawa for ankle fractures could be adopted. (Stiell et al. 1993) The best performing candidate clinical decision rule was based on just four clinical features: namely presence of any one of a) palpable bony step, b) sub-conjunctival hemorrhage with no posterior limit, c) anaesthesia or paraesthesia to lip/cheek or side of nose, or d) palpable emphysema. We observed that more than 75% of patients undergoing facial bone radiography did not go on to demonstrate a radiographically displaced fracture, and felt it was important to explore whether use of this candidate decision rule could reduce reliance on radiographs at the triage stage. By definition, a clinical decision rule derived in one dataset will perform well in the same data, so ideally we would have performed this exploration in a different dataset. We are not aware of other units with prospectively obtained

systematic recording of these clinical features, so we performed evaluation using our own data. We believe this provides the best currently available estimate of the radiographic dose reduction which could be achieved by introducing clinical decision rules.

The main benefit of clinical decision rules would be prompt and correct identification of patients who require further investigation and imaging. Patient safety would be enhanced through a reduction in exposure to ionizing radiation which we estimate at 55.5% (95% CI 49.0% - 61.9%), with all fractures identified at the triage stage, as explored in figure 1. In addition to this dose reduction, we would envisage broader benefits for both patients and hospitals, such as quicker time to a triage decision, reduced utilization of equipment and reduced demands on radiographers and radiologists.

In this study, we classified clinically important fractures requiring surgical review as fractures that were seen to be displaced on plain radiography (OM10 and 30). Therefore it is possible that undisplaced fractures were not included in our classification. Is our practice to manage undisplaced fractures non-operatively however, and for that reason we felt that this was an appropriate classification for a clinical decision making tool.

Unlike zygomatico-maxillary fractures, isolated orbital floor fractures are not reliably demonstrated on plain film radiographs, and may require CT imaging for diagnosis. We classified radiographic findings in this study based on plain films, and were aware misclassification would be high for isolated orbital floor fractures. Therefore, we did not analyse these injuries and the findings of this study are not applicable to isolated orbital floor fractures, which have a specific clinical presentation (*Roth et al.* 2010). There are additional clinical scenarios where CT is the investigation of choice, for example characterizing complex fractures and panfacial trauma. We do not suggest that clinical examination replaces or provides the same information as these investigations, and believe that patients with displaced fractures should receive all appropriate imaging. Rather, this pilot study focuses on the use of plain films to exclude the presence of a displaced fracture at triage stage, where we believe there is scope for radiographic dose reduction.

In keeping with previously published evidence,(*Salentijn et al.* 2014a) this study found no association between severe facial swelling and displaced zygomatico-maxillary bony injuries (ROC area 0.49,  $p$  for correlation 0.78). One interpretation for this finding is that facial swelling alone may not be sufficient indication for radiographic examination. In patients presenting with severe facial swelling or pain, questionable mechanisms of injury or in the presence of other injuries, radiographic investigation should ultimately be based on sound clinical history, examination and individual judgement.

Other studies have reported an association between severe neurological injuries requiring neurosurgical management and facial bone fractures.(*Pappachan and Alexander* 2006, *Salentijn et al.* 2014b) The anatomical site of injury appears important, in that fractures in the lower portion of the facial skeleton are less likely to co-present with neurological injury than fractures in the upper portion of the facial skeleton(*Lee et al.* 1987, *Chang et al.* 1994). By contrast, this study did not identify a statistically significant association. This may be due to the demographics and methodology within this study. We identified patients with neurological head injury based on history and clinical assessment in the Emergency Department. Our study only included patients who were able to cooperate with plain facial radiography. By definition, patients who had suffered major head injuries rendering them uncooperative or unconscious were excluded from our analysis. Furthermore, alcohol is a major factor in the aetiology of facial injuries arising from accidents or interpersonal violence (*Conway et al.* 2010) and the effects of alcohol can mask or emulate a neurological head injury. This means that a reliable diagnosis is often made at a later stage following secondary survey investigations according to advanced trauma life support (ATLS). We recommend our findings are not applicable to instances of complex multisystem trauma, including neurological head injury. Moreover, although we present findings from over 200 patients, the data presented here were

gathered in a single district general hospital in the United Kingdom, and may not be representative of the pattern of facial injuries found elsewhere.

## **CONCLUSION**

We believe there is a need for clinical decision rules for zygomatico-maxillary fractures. The presence of a) palpable bony step, b) bony asymmetry, c) lateral sub-conjunctival haemorrhage with no posterior limit, d) anaesthesia or paraesthesia to lip/cheek or side of nose and e) palpable emphysema are all specific features of displaced zygomatico-maxillary fracture, (specificity all >75%) and patients presenting with these features may benefit from investigation and radiographic imaging. Clinical decision rules for zygomatico-maxillary fractures appear feasible, and within this study a patient selection protocol based on just four clinical features performed well by identifying 100% of patients with radiographically displaced fractures (95% CI 93.4% - 100.0%) with high specificity (72.6%, 95% CI 65.3% - 79.0%). Implementation of a decision rule might reduce radiographic burden by 55% whilst still identifying all patients with clinically relevant injuries. Further research is required to clarify the relationship between neurological head injury and displaced fractures. Well-powered, multi-centred prospective data collection is required to construct a validated clinical decision making tool for the assessment of facial injuries and suspected zygomatico-maxillary fractures.

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**Conflicts of interest:** none

## TABLES

Clinical feature	Sensitivity	95% Confidence interval		Specifi city	95% Confidence interval		ROC area	95% Confidence interval		Test for correlation
Palpable Bony Step*†	83.3	70.7	92.1	96.0	91.9	98.4	0.90	0.84	0.95	< 1.0E-08
Bony Asymmetry*†	74.1	60.3	85.0	96.0	91.9	98.4	0.85	0.79	0.91	< 1.0E-08
Sub-conjunctival Haemorrhage with No Posterior Limit*†	55.6	41.4	69.1	96.6	62.7	98.7	0.76	0.69	0.83	< 1.0E-08
Anaesthesia or Paraesthesia to lip/cheek or side of nose*†	59.3	45.0	72.4	78.9	72.1	84.7	0.69	0.62	0.76	4.1E-08
Restricted Movement of Mandible*	35.2	22.7	49.4	83.4	77.1	88.6	0.59	0.52	0.66	0.0032
Palpable Emphysema*†	18.5	9.3	31.4	98.3	95.1	99.6	0.58	0.53	0.64	1.98E-06
Neurological Head Injury	14.8	6.6	27.1	76.6	69.6	82.6	0.46	0.40	0.51	0.18
Malocclusion	5.6	1.2	15.4	11.0	97.9	100.0	0.53	0.50	0.56	0.0016
Pain on Biting	22.2	12.0	35.6	52.9	76.4	88.1	0.53	0.46	0.59	0.40
Double Vision	3.7	0.5	12.7	89.7	84.2	93.8	0.47	0.43	0.50	0.14
Pupils Equal and React to Light	100.0	93.4	100.0	1.1	0.1	4.1	0.51	0.50	0.51	0.43
Enophthalmous	3.7	0.5	12.7	98.9	95.9	99.9	0.51	0.49	0.54	0.21
Cervical Spine Injury	0.0	0.0	6.6	98.9	95.9	99.9	0.49	0.49	0.50	0.43
Severe Soft Tissue Swelling	40.7	27.6	55.0	57.1	49.5	64.6	0.49	0.41	0.57	0.78
Reduced Visual Acuity	3.7	0.5	12.7	97.1	93.5	99.1	0.50	0.48	0.53	0.75
Diplopia	5.6	1.2	15.4	95.4	91.2	98.0	0.50	0.47	0.54	0.77
Multiple or Severe Trauma	11.1	4.2	22.6	89.1	83.6	93.3	0.50	0.45	0.55	0.96

**Table 1 – Performance of clinical features as a predictor of radiographic evidence of displaced fracture.** A ROC area of 1 indicates that the predictor perfectly predicts the presence of the outcome. A ROC area of 0 indicates that the presence of the predictor perfectly predicts absence of the outcome. A ROC area of 0.5 indicates the predictor performs no better than chance in predicting

the outcome. \* Indicates features where 95% confidence intervals for the ROC area exclude 0.5. The test for correlation tests the null hypothesis that there is no correlation between the clinical feature and the presence of a fracture. † Indicates features which show evidence for correlation after correction for multiple testing.

Decision rule evaluated	Presence of
	Palpable bony step OR Sub-conjunctival haemorrhage with no posterior limit OR Anaesthesia or paraesthesia to lip/cheek or side of nose OR Palpable emphysema
<b>Sensitivity</b>	100.0%
<b>95% CI</b>	93.4%
	100.0%
<b>Specificity</b>	72.6%
<b>95% CI</b>	65.3%
	79.0%
<b>ROC area</b>	0.86
<b>95% CI</b>	0.83
	0.90
<b>Positive predictive value</b>	52.9%
<b>95% CI</b>	42.8%
	62.9%
<b>Negative Predictive Value</b>	100.0%
<b>95% CI</b>	97.1%
	100.0%
<b>Odds Ratio</b>	NA
<b>95% CI</b>	36.79
	NA

**Table 2:** Diagnostic criteria for the best performing candidate decision making rule

## **CAPTIONS TO ILLUSTRATIONS**

**Figure 1 – Implications of adopting the decision rule described in table 1.**

Retrospective evaluation of the implications of adopting a clinical decision rule within this dataset.



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